UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	)	Consolidated No. 09-cv-11267 (GAO)
	)	**Leave to file granted on February 16, 2012**

DEFENDANTS' JOINT REPLY TO LEAD PLAINTIFFS' JANUARY 17, 2012 NOTICE OF SUPPLEMENTAL AUTHORITY

A Notice of Supplemental Authority is supposed to inform the Court of newly decided cases that bear on a matter under advisement. It is not an opportunity to cite *old* cases omitted from prior briefs, add arguments not previously made, or rehash well-trodden ground. Regrettably, Lead Plaintiffs' *latest* such Notice (the "Supp. Notice II"), Docket No. 96, does all three.

Lead Plaintiffs claim that three "relevant" decisions lend "further support" to the argument that Genzyme committed fraud by failing to disclose receipt of a Form 483 from the FDA. According to the plaintiffs, Genzyme should have disclosed in *2007* that it was not in compliance with current Good Manufacturing Practices ("cGMPs") because in *2008* the FDA issued a Form 483 making observations about Genzyme's manufacturing, and those remarks were subsequently held to be valid in *2009*. And the plaintiffs assert that the same observations should have prompted Genzyme to disclose that vesivirus 2117 contaminated two bioreactor vessels prompting them to shut down, and obliged Genzyme to predict delays in approval to manufacture large-vessel production Lumizyme (Myozyme).

None of the cases the plaintiffs now cite remotely support those illogical claims.

***Wilkof v. Caraco Pharm. Labs., Ltd.*, 2010 WL 4184465 (E.D. Mich. Oct. 21, 2010)**

Wilkof was decided some sixteen months ago, and fully three months *before* oral argument on the motion to dismiss. If the decision had any significance for the plaintiffs' case, it should have been referenced then, not trumpeted now as "supplemental" authority that receipt of a Form 483 triggers a disclosure obligation.

More importantly, the case does not stand for that singular proposition. In *Wilkof,* Caraco Pharmaceutical Laboratories' disclosure that it was "substantially compliant" with cGMPs was subject to "objective verification." 2010 WL 4184465 at *6. The plaintiffs did not rely on the company's receipt of a Form 483 alone. Rather, the complaint's charge that the representation of "substantial compliance" was false hinged upon the statements of ten separate witnesses who "describe[d] in great detail the severity of the manufacturing problems at Caraco," and whose allegations corroborated and "were consistent with" the FDA's observations. *Id*. According to the court, that abundant evidence of non-compliance – rather than the Form 483 by itself – permitted the inference of intentional or recklessly misleading disclosure. The case accordingly does not stand for the proposition that receipt of a Form 483 is itself a disclosure event; that a Form 483 itself establishes noncompliance with cGMPs; or that "notice" of *possible* manufacturing issues requires predictions of subsequent regulatory findings. It was the *actual* evidence of non-compliance that justified a charge of wrongful omission. Most importantly, the decision cannot trump the local decision in *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142 (D. Mass. 2007) (noting that even an FDA warning letter – a step that follows a Form 483 – merely conveys "the Agency's position on a matter" in an "informal and advisory" manner, and "'does not commit FDA to taking enforcement action'"), *rev'd on other grounds,* 523 F.3d 75 (1st Cir. 2008).

Moreover, and quite apart from its failure to support an independent duty to disclose *potential* non-compliance with cGMPs after receipt of a Form 483, nothing in *Wilkof* can be read to support the plaintiffs' illogical charge that the FDA's observations should have prompted Genzyme to predict delays in approval of the Lumizyme biologics license application ("BLA"). The two issues are separate; they turn on different regulatory standards; the FDA itself set a target date for awarding the BLA *after* issuing the Form 483, severing any connection between the BLA and the inspectional observations; and nothing in the complaint factually links the discrete matters. Likewise, nothing in *Wilkof* remotely supports the plaintiffs' *scienter* allegations. The plaintiffs marry unrelated facts and ignore temporal sequence. It is not rational to assert that Genzyme *must have known* that its optimism for resolving FDA concerns about cGMP compliance was misplaced in the spring of 2009 because the Allston Facility *subsequently* sustained a viral contamination. Reasoning backward to pour ostensibly guilty knowledge about different issues into Genzyme's head is not permissible as a matter of law or logic.

***In re MannKind Sec. Actions*, 2011 WL 6327089 (C.D. Cal. Dec. 16, 2011)**

MannKind does not address Form 483s at all. The opinion does not deal with either inspectional observations, compliance with good manufacturing practices, licensing of biologic facilities, or viral contamination. It does not even deal with what inferences can be drawn about a company's "knowledge" of likely FDA action on any subject as a result of "notice" from the FDA. Rather, *MannKind* addresses an issuer's *false* statement that the FDA agreed to certain testing protocols, and its *false* assurances that the agency was comfortable substituting one version of a medical device for another, when the agency had done nothing of the sort. The only thing *MannKind* has in common with this case is that both involve pharmaceutical companies.

It is one thing to attribute deliberately false statements to the FDA, and quite another to claim that Genzyme "should" have figured out what the FDA "might" do in the future and disclosed it. Likewise, it is obvious that an inference of scienter can arise when false disclosures are made by an issuer like MannKind whose continued financing depends upon its stock price remaining above a specified level. And it is equally obvious that no such inference arises when hindsight alone supplies the basis for the plaintiffs' charge of insufficient disclosure. But those are the differences between *MannKind* and the present case. There simply is nothing in *MannKind* that the Court could conceivably point to in an opinion that decides the present motion in favor of *either* party.

***Shapiro v. Matrixx Initiatives, Inc.*, 2011 U.S. Dist. LEXIS 111159 (D. Ariz. Sept. 26, 2011)**

Unlike *MannKind*, the six-month old *Matrixx* decision at least uses the phrase "Form 483" – but only once, as part of the factual background to the decision. The plaintiff did *not* claim that the company's receipt of a Form 483 should have been disclosed, or even that receipt of the Form 483 put Matrixx on "notice" of adverse events it should have revealed. So the Lead Plaintiffs' contention here – that *Matrixx* shows that the "contents" of the Form 483 issued to Genzyme in October 2008 "provide a sufficient basis for alleging the existing of material (and indeed 'systemic') problems . . . that were never adequately disclosed," Supp. Notice II at 4 – is a non-starter. Since *Matrixx* does not even discuss the "contents" of a Form 483 or its significance for disclosure, the plaintiffs' argument that *Matrixx* has any relevance here is untenable. A case that does not address an issue is hardly compelling authority on that issue.

The plaintiffs' other suggestion – that *Matrixx* supports their allegations of scienter – is equally baffling. According to the Lead Plaintiffs, Genzyme's "partial disclosure of *some* FDA concerns . . . does *not* negate the inference of their [sic] scienter with respect to adverse

information that they [sic] continued to withhold." Supp. Notice II at 3-4 (emphasis in original). To be sure, in *Matrixx*, an inference of scienter arose from the disclosure of several lawsuits against the company alleging that Zicam caused anosmia[1] while simultaneously concealing the existence of at least 800 other customer complaints of the same problem. The juxtaposition of the disclosed lawsuits with the undisclosed complaints permitted the inference that Matrixx deliberately concealed the extent of adverse reactions to its product. But here, in sharp contrast, the plaintiffs do not identify any *facts* that Genzyme allegedly "continued to withhold." They only point to events that happened *later*, to claim that Genzyme "must have" known "facts" *earlier*. The missing links between *Matrixx* and this case, then, are adverse knowledge, in Genzyme's head, at an earlier time than ultimately revealed, and deliberately omitted for an impermissible motive.

* * *

For these reasons, and for those stated in Genzyme's papers supporting its Motion to Dismiss, the plaintiffs' Complaint should be DISMISSED.

[1] "Anosmia" is loss of the sense of smell.

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Respectfully submitted,

/s/ John D. Donovan, Jr.

John D. Donovan, Jr. (BBO# 130950)
Robert G. Jones (BBO# 630767)
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600
(617) 951-7000 (Tel)
(617) 951-7050 (Fax)

Counsel for the Defendant Genzyme Corporation

/s/ Michael T. Marcucci

John D. Hanify (BBO# 219880)
Michael T. Marcucci (BBO# 652186)
JONES DAY
100 High Street
Boston, Massachusetts 02110-1781
(617) 960-3939 (Tel)
(617) 449-6999 (Fax)
mmarcucci@jonesday.com

Counsel for Individual Defendants

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on February 16, 2012.

/s/ John D. Donovan Jr.
John D. Donovan, Jr.